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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,455	10/24/2005	Kozo Takeda	TAKEDA19	2196
1444 7590 06/27/2008 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303				
EXAMINER				
MONDESI, ROBERT B				
ART UNIT		PAPER NUMBER		
1652				
MAIL DATE		DELIVERY MODE		
06/27/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/527,455

Applicant(s)

TAKEDA ET AL.

Examiner

ROBERT B. MONDESI

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-22 is/are pending in the application.
4a) Of the above claim(s) 8, 11-16 and 21-22 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 4-7, 9, 10 and 17-20 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

This Office action is in response to the amendment filed April 2, 2008.

Status of the claims

Claims 2-3 are canceled. **Claims 1 and 4-22** are pending. **Claims 8, 11-16 and 21-22** are withdrawn for pertaining to nonelected subject matter (**Claims 21-22** pertain to a product that is prepared by the method the invention and a method of manufacturing a medical protein formulation and are therefore placed in a different Groups of inventions, the confusion with regards to these claims was initially created because the claims were originally improperly multiply dependent. **Claims 1, 4-7, 9-10 and 17-20** are presently under examination.

Withdrawal of Objections and Rejections

The objections and rejections not explicitly restated below are withdrawn due to applicants' response in amendment filed April 2, 2008.

Claim Rejections - 35 USC § 112

The rejection of **Claims 2-3** under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because applicants have canceled the claims.

Maintenance of rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1652

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6 and 17 remain rejected under 35 U.S.C. 102(b) as being anticipated by Faupel et al., United States Patent No. 4,971,670.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4-5 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Faupel et al., United States Patent No. 4,971,670 in view of EP 0313343.

Claims 1, 9-10 and 19-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Faupel et al., United States Patent No. 4,971,670 in view Vedantham et al. US Patent Publication No. 2003/0166869.

The above rejections were explained in the previous Office action.

Response to applicants' arguments

In regards to the rejection of **claims 1, 6, and 17** under 35 U.S.C. 102(b) as being anticipated by Faupel et al., United States Patent No. 4,971,670 applicants assert that the aqueous solution in the claimed method must have a molarity of 100 mM or less, or an ionic strength of 0 to 2, as stated in the specification as filed at page 14, lines 6-12. This concentration of the aqueous solution is critical to the presently claimed method. There is no such disclosure of concentration of the solution in Faupel. Applicants assert further that Faupel relates to a separation or purification method of a neutral chemical compound by using an isoelectric focusing electrophoretic process. However, there is neither teaching nor suggestion in Faupel of a method for removing impurities such as DNA contaminants and viruses as particles from a solution by adjusting the pH and the concentration of the solution to obtain particles of the contaminants as claimed herein.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., an ionic strength of 0 to 2; impurities such as DNA contaminants and viruses) are not recited in the rejected **claim(s) 1, 6 and 17** . Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In regards to the rejection of claims 1 and 4-5 under 35 U.S.C. 103(a) as being unpatentable over Faupel et al., United States Patent No. 4,971,670 in view of EP 0313343 applicants assert that there is neither teaching nor suggestion in Faupel or EP 0313343 (Naveh) of a method for removing impurities such as DNA contaminants and viruses as particles from a solution by adjusting the pH and the concentration of the solution to obtain particles of the contaminants as claimed herein. Applicants also assert that the concentration of 100mM or less in the presently claimed method is the concentration of the protein-containing solution. The concentration of the protein-containing solution is one important component of the claimed method. The conductivity of Naveh is 13 ms/cm, which is equivalent to 1300 mS/m, which is more than an order of magnitude greater than the 300 mS/m claimed herein.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., impurities such as DNA contaminants and viruses) are not recited in the rejected **claim(s) 1 and 4-5** . Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Furthermore, applicants need to be made aware of the fact that as presently claimed the conductivity range of the solution is 0-300 mS/m which essentially makes the limitation a non-limitation because 0 mS/m is within the scope of the rejected claims. So in other words the solution has no conductivity ! Therefore the limitation can not be given patentable weight since 0 equates to lack of existence. The same concept applies to applicants'

newly amended claim 1 wherein the concentration of the solution/protein is 100mM or less (Zero is a number that falls within the scope of the instantly claimed invention).

In regards to the rejection of the **claims 1, 7, 9-10 and 19-20** under 35 U.S.C. 103(a) as being unpatentable over Faupel et al., United States Patent No. 4,971,670 in view Vedantham et al. US Patent Publication No. 2003/0166869, applicants assert that Vendantham discloses a method for purifying proteins such as DNA contaminants, but the method used is hydroxyapatite chromatography, which has nothing to do with the particle-forming process claimed herein. As defined by Vendantham, hydroxyapatite chromatography is chromatography using ceramic hydroxyapatite as an absorbent. The present method does not remove impurities from a protein solution by absorption, such as by affinity chromatography, but by forming particles of the contaminants and then removing the particles.

Applicants' arguments have been considered but have not been found persuasive. The examiner is confused as to what exactly the applicants are asserting. **Claim 19** has a specific limitation in line 6 that cites the use of affinity chromatography yet the arguments assert that the "the present method does not remove impurities from a protein solution by absorption, such as by affinity chromatography, but by forming particles of the contaminants and then removing the particles".

Furthermore in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., forming particles of the contaminants and then removing the particles and the negative limitation of not using ceramic hydroxyapatite as an

Art Unit: 1652

absorbent) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

New Objection(s) and Rejection(s)

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-7, 9-10 and 17-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have amended claim 1 in order to include the new limitation "having a concentration of 100mM or less". Applicants have submitted on the record that there is no literal support for the newly added limitation and have indicated that the limitation was previously disclosed in claim 2; however this is not accurate since claim 2 is directed to the conductivity of the solution and is completely silent with regards to the concentration of the protein in the sample. This cannot be considered as inherent support for the applicants amend as argued on the record on page1 of the remarks filed April 2, 2008.

Therefore the question is raised as to whether applicants' amendment to claim has raised new issues with regards to new matter. The failure to meet the written description requirement of 35 U.S.C. 112, first paragraph, commonly arises when the claims are changed after filing to either broaden or narrow the breadth of the claim limitations, or to alter a numerical range limitation or to use claim language which is not synonymous with the terminology used in the original disclosure. To comply with the written description requirement of 35 U.S.C. 112, para. 1, or to be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, or 365(c), each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-7, 9-10 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have amended claim 1 in order to include the new limitation "having a concentration of 100mM or less"; however the is new limitation is problematic due to the fact the range also include zero. Therefore the scope of the claims includes a protein containing sample that has a concentration of protein that is Zero.

Claims 4-7, 9-10 and 17-20 are dependent claims that do not remedy the deficiencies of the independent claim that they depend from.

Conclusion

No claims are allowed

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **ROBERT B. MONDESI** whose telephone number is (571)272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashed Nashaat can be reached on (571)272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert B Mondesi/
Primary Examiner
Art Unit 1652
June 24, 2008